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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/175,017	10/19/1998	IRVING BOIME	295002000590	6407

25225 : 7590 11/18/2002

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EXAMINER

SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/18/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.



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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 9/9/02

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-12, 21-28 is/are pending in the application.
Of the above, claim(s) 4, 7-9, 22-24, 26-28 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-3, 5, 6, 10-12, 21, 25 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-12, 21-28 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

PTO: 1996-421-632/4020R

Part III: Detailed Office Action

Claims 1-3, 5, 6, 10-12 and newly submitted claim 21 are under consideration. As the prior art rejection of record addresses the limitations of newly submitted claim 25, it is rejoined with the elected claims.

5 The rejection of claims under 35 U.S.C. § 112, first paragraph is withdrawn in view of applicants' arguments and/or amendments.

Formal Matters:

10 The new title of the invention is acknowledged.

 Claims 6 and 10-12 remain objected to for encompassing non-elected species, there being no allowable generic claim. If allowability of the elected species is determined and the genus remains non-allowable, applicants will be required to amend the claims to limit to the elected species.

15 **Objections and Rejections under 35 U.S.C. §112:**

 The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20 Claims 1-3, 5, 6, 10-12, 21 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25 Claims 1, 11 and 12 are indefinite because they have been amended to have the negative limitation that "if β^1 is CG β then β^2 is not FSH β ". However, as the two formulae given in the claims are complementary, it is not clear what is excluded, as there is no exclusion that if β^2 is CG β then β^1 is not FSH β .

 Claim 6 is indefinite because it is not clear what the basis of comparison is for "lowered" LH agonist activity. Claims 8 and 10 are similarly indefinite.

Claim 21 is indefinite for using the word "as" in the second line of the claim. Amendment to read --is-- would be remedial.

5 **Rejections over Prior Art:**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35
20 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

 Claims 1-3, 5 and 6 remain, and claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over L. Seethalakshmi et al., Journal of Urology 144:1489-1492, 1990 in view of R.K.
25 Hyde et al., Biology of Reproduction 54(Suppl. 1) :105, Abstract 193, 1996 and D. Ben-Menahem et al., Abstract OR28-3 presented at Endo 98, Endocrine Society, 1998.

 This rejection is applied to the claims which have been amended to include the negative limitation of claims 11-12, as well as to claims 11-12 themselves, in view of the indefiniteness of the negative limitation, see rejection under 35 U.S.C. § 112, second paragraph, above. It is not
30 clear that the obvious species is excluded from the claims.

 Applicants traversal in paper number 18 filed 9/12/02 has been fully considered but is not deemed persuasive. Just as the Examiner is aware that co-authorship does not raise the presumption

of co-invention, applicant's Attorney is surely aware that the proper means of overcoming a rejection such as this is submission of a *Katz* declaration. Further, although both the Ben-Menahem and Hyde references were cited, such was done in the interest of thoroughness, and the rejection would stand if either (but not both) reference were removed.

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Claims 1-3, 5, 6, 11 and 12 remain, and newly introduced claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over G. De Rosa et al., *Annales d'endocrinologie* 48(6):468-472, 1987 (Abstract only) in view of R.K. Hyde et al., *Biology of Reproduction* 54(Suppl. 1) :105, Abstract 193, 1996 and D. Ben-Menahem et al., Abstract OR28-3 presented at Endo 98, Endocrine Society, 1998.

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Applicants argument that administration to children with undescended testes is not a treatment for fertility is "not the type of treatment envisioned" and does not meet the limitation of being a fertility treatment has been fully considered but is not deemed persuasive. The issue in question is what the claims actually say, and not what might have been envisioned. It is well known in the art that undescended testes cause infertility in adult males. Therefore, although certainly fertility is not an *immediate* issue for a twelve year old boy, treatment to cause testis descent would have the effect of increasing the fertility of the individual. Increasing fertility does not require that such fertility be used for productive purpose within a given time frame. Therefore, contrary to applicants arguments, the person of ordinary skill in the art, having the DeRosa, and Hyde and/or Ben-Menahem papers in hand, would have immediately envisioned the co-administration of either LH β α and FSH β or the coadministration of FSH β α and LHB for the purpose for treating undescended testes. Applicants have provided no support for their assertion that it is not clear that HMG is comprised of LH and FSH. See the abstract by Duijkers et al., below, that clearly states: "Human menopausal gonadotropin (hMG) contains equal amounts of FSH and LH activity".

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Advisory Information:

No claim is allowed.

Claims 10 and 21 are free of the prior art as there is no motivation provided by the prior art to use two β subunits from the same hormone, and would be allowable if amended to overcome the rejection under 35 U.S.C. § 112, second paragraph.

No claim is allowed.

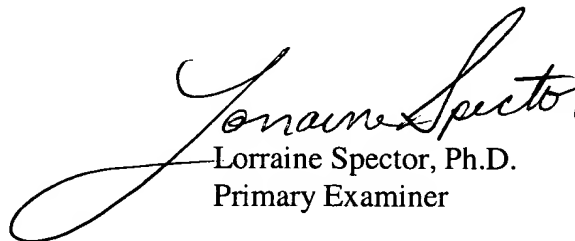
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.


Lorraine Spector, Ph.D.
Primary Examiner

LMS
09/175017.2
11/15/02